Consumer Letter
(Accu-Chek Insight Key Lock)

Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system:
Update of the handling instructions regarding the Key Lock function

Dear Customer [*please personalize*],

We have recently received feedback from people with diabetes using the Accu-Chek Insight system that they experienced an accidental unlocking of the pump keys and an unintentional operation of the system. We have immediately investigated this feedback and identified the handling instructions and user manual of the Accu-Chek Insight insulin pump to be not detailed enough regarding the description of the key lock function. This could potentially be misinterpreted or lead to unintentional, accidental operation of the pump. Such unintentional operation could potentially result in an under- or overdose of insulin and to severe health consequences as e.g. hyper- or hypoglycemia.

As patient safety is our top priority, Roche Diabetes Care has started to enhance the handling instructions for the Accu-Chek Insight system with immediate effect. In doing so, we aim to ensure that every user of the Accu-Chek Insight insulin pump knows how to operate and wear the system appropriately. These measures will help reduce the risk of an unintentional activation of the pump or accidental insulin delivery.

Important information:

1. Please always prevent any pump contact with other objects in the pocket such as keys, coins or phones. Such objects could damage the pump or accidentally press the Quick Bolus keys or the keys on the front of the pump. This could potentially result in an unintentional bolus delivery or unlocking of the pump. Such an accidental operation of the system can be detected by the vibration or acoustic alarm of the pump.

2. Please be aware that the key lock function of the Accu-Chek Insight insulin pump disengages ***only*** the buttons on the front of the insulin pump.
3. Please be aware that the automatic key lock function of the pump is programmed to be activated 30 seconds after the last key was pressed. This interval can be changed based on your individual needs from 4 up to 60 seconds.

4. The Quick Bolus keys on the top of the Accu-Chek Insight insulin pump are ***not*** disengaged by the activated key lock function. To activate the Quick Bolus function, one of the keys needs to be pressed for more than 3 seconds. The Quick Bolus keys are designed to enable a quick bolus delivery as well as to cancel a bolus in any situation.

Recommendations for appropriate wearing and operation of the pump:

1. Please wear the pump in such a way that the Quick Bolus keys on the top of the pump cannot be pressed accidentally, in particular when carrying the pump in a pocket or wearing it under clothing (e.g. do not wear it in a pocket together with a car key, coins or other objects).
2. Please ensure that the keys on the front of the pump cannot be pressed accidentally, especially during the night while you are asleep.
3. Please make sure to adjust the timeout interval for the key lock function to your individual needs. For children, it is recommended to use the minimum timeout interval of 4 seconds. This means that the pump will automatically lock itself 4 seconds after an accidental unlocking, if no other key has been pressed in the meantime.
4. Parents and caregivers should advise children ***not*** to press any pump keys. Children should be taught to only press the pump keys if a pump operation is required, to avoid any unintentional operation of the pump.
5. For children and adolescents using the Accu-Chek Insight system or users who are concerned that they may activate the Quick Bolus function unintentionally, we recommend setting the Quick Bolus increment to the minimum, i.e. 0.1 units.

These additional instructions provided in this letter will support you in the correct, reliable and satisfactory use of their Accu-Chek Insight insulin pump system. We sincerely apologize for any inconvenience this may have caused you.

Your national competent authority, healthcare professionals, distributors and retailers have been informed about this field action.

Thank you in advance for your understanding and co-operation. If you need any additional advice on the operation and wearing of the Accu-Chek Insight system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. to obtain a detailed training at any time.

Kind regards,
Roche Diabetes Care

Distributor/Retailer Letter (Accu-Chek Insight Key Lock)

Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system:
Update of the handling instructions regarding the Key Lock function

Dear Distributor [*please personalize*],

We have recently received feedback from people with diabetes using the Accu-Chek Insight system that they experienced an accidental unlocking of the pump keys and an unintentional operation of the system. We have immediately investigated this feedback and identified the handling instructions and user manual of the Accu-Chek Insight insulin pump to be not detailed enough regarding the description of the key lock function. This could potentially be misinterpreted or lead to unintentional, accidental operation of the pump. Such unintentional operation could potentially result in an under- or overdose of insulin and to severe health consequences as e.g. hyper- or hypoglycemia.

As patient safety is our top priority, Roche Diabetes Care has started to enhance the handling instructions for the Accu-Chek Insight system with immediate effect. In doing so, we aim to ensure that every user of the Accu-Chek Insight insulin pump knows how to operate and wear the system appropriately. These measures will help reduce the risk of an unintentional activation of the pump or accidental insulin delivery.

Important information:

1. Please advise your customers using the Accu-Chek Insight system to always prevent any pump contact with other objects in the pocket such as keys, coins or phones. Such objects could damage the pump or accidentally press the Quick Bolus keys or the keys on the front of the pump. This could potentially result in an unintentional bolus delivery or unlocking of the pump. Such an accidental operation of the system can be detected by the vibration or acoustic alarm of the pump.

2. Please be aware that the key lock function of the Accu-Chek Insight insulin pump disengages ***only*** the buttons on the front of the insulin pump.
3. Please be aware that the automatic key lock function of the pump is programmed to be activated 30 seconds after the last key was pressed. This interval can be changed based on

patients'
individual needs from 4 up to 60 seconds.

4. The Quick Bolus keys on the top of the Accu-Chek Insight insulin pump are ***not*** disengaged by the activated key lock function. To activate the Quick Bolus function, one of the keys needs to be pressed for more than 3 seconds. The Quick Bolus keys are designed to enable a quick bolus delivery as well as to cancel a bolus in any situation.

Recommendations for appropriate wearing and operation of the pump:

1. Please advise your customer using the Accu-Chek Insight system to wear the pump in such a way that the Quick Bolus keys on the top of the pump cannot be pressed accidentally, in particular when they carry the pump in a pocket or wear it under clothing (e.g. do not wear it in a pocket together with a car key, coins or other objects).
2. Users of the Accu-Chek Insight system are advised to ensure that the pump keys on the front of the pump cannot be pressed accidentally, especially during the night while they are asleep.
3. Users of the Accu-Chek Insight system should make sure to adjust the timeout interval for the key lock function to their individual needs. For children, it is recommended to use the minimum timeout interval of 4 seconds. This means that the pump will automatically lock itself 4 seconds after an accidental unlocking, if no other key has been pressed in the meantime.
4. Parents and caregivers should advise children ***not*** to press any pump keys. Children should be taught to only press the pump keys if a pump operation is required, to avoid any unintentional operation of the pump.
5. For children and adolescents using the Accu-Chek Insight system or users who are concerned that they may activate the Quick Bolus function unintentionally, we recommend setting the Quick Bolus increment to the minimum, i.e. 0.1 units.

These additional instructions provided in this letter will support people with diabetes in the correct, reliable and satisfactory use of their Accu-Chek Insight insulin pump system. We sincerely apologize for any inconvenience this may have caused you and your customers.

This issue is only affecting the Accu-Chek Insight system. Your national competent authority, users of the Accu-Chek Insight system and healthcare professionals have been informed about this field action.

Thank you in advance for your understanding and co-operation. If you need any additional advice on the operation and wearing of the Accu-Chek Insight system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. to obtain a detailed training at any time.

Kind regards,
Roche Diabetes Care